

REMARKS

Claims 50, 51 and 80-84 are under examination.

Applicants have elected Group I with traverse on the following grounds. The Examiner cites the limitation in claim 50 relating to "at least one polymorphism" in making a subsequent restriction but there is more to the claim than this. The claim recites that it is a method for determining risk for cardiovascular disease and that the risk is determined by determining the presence of a polymorphism in ABCA1 protein, relative to the sequence of SEQ ID NO: 2, in a sample from a patient wherein the ABCA1 polymorphism is indicative of a risk for cardiovascular disease.

The Examiner appears to believe that limitation to a particular polymorphism is needed in order to search this claim. Applicants have amended the claims (see accompanying Amendment) to simplify them. Applicants counter that this claim 9 and thus the claims dependent from it) can be searched without any reference to a sequence. Any search of the patentability of claim 50 must begin with the generic aspects of the claim.

Claim 50 rests on a relationship between ABCA1 protein and cardiovascular disease, which relationship was first identified by Applicants. Otherwise, no one in the art would know that functioning of ABCA1 is related to cardiovascular disease. As such, no one could have reported a relationship between a polymorphism in ABCA1 and cardiovascular disease because Applicants were the first to teach the physiological function of this protein. Thus, searching sequences is irrelevant. Furthermore, even if a polymorphism in the sequence was reported in the literature it would be irrelevant to claim 50 because the latter requires determining a risk of cardiovascular disease, which no one would have done because they did not know about this prior to Applicants' teaching. Again, no search of sequences is required.

Because the invention recited by claim 50 is dependent on a relationship between ABCA1 and risk of cardiovascular disease, any limitation of the claim to a particular polymorphism, or set of polymorphisms, would unduly limit the claim and compromise Applicants' patent rights by greatly reducing the breadth of the protected invention.

The art of determining a polymorphism in a protein or gene sequence is well known and a currently routine matter. The polymorphisms disclosed in Figure 11 are intended to support the claimed method and not to limit it. If any other polymorphism is to be evaluated for its effect on ABCA1, Applicants provide a simple assay for the activity of ABCA1 protein that involves determining transport of a labeled lipid across a cell membrane (see application at page 96, lines 5-14). However, this is not required because the claim is directed to a method for determining risk and not to a diagnostic procedure for cardiovascular disease.

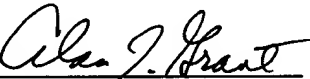
The Examiner also suggests that Applicants should refer to the polymorphisms by SEQ ID NO: instead of designating the polymorphism. All polymorphisms are relevant to SEQ ID NO: 2, the amino acid sequence of ABCA1, and this recitation has been added to claim 50.

Applicants suggest that, if a generic claim is not found allowable so as to encompass polymorphisms in ABCA1 per se, then an interview should be set up between Applicants' agent and the Examiner and his supervisor (before further examination time is expended) as a means of resolving this issue and thereby not unduly limiting the claims of the application or extending prosecution. Thus, Applicants election of Group I should be interpreted by the Examiner as an election of species for examination purposes only and not as the election of an invention.

Applicants have included herewith a request for a 2 month extension of time and the relevant fee. No additional fee is believed due in filing this paper. If any fee is due,

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Applicant requests that the Commission charge such fee to Deposit Account No. 03-0678.

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 Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
 Alan J. Grant, Esq.	<u>9/19/03</u> Date

Respectfully submitted,



Alan J. Grant, Esq.
Reg. No. 33,389

CARELLA, BYRNE BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Six Becker Farm Road
Roseland, NJ 07068
Phone: 973-994-1700
Fax: 973-994-1744